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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/373,230	08/12/1999	HARUKI OKMURA	OKAMURA=2E	2359
1444 7590 02/21/2008 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER JIANG, DONG	
			ART UNIT 1646	PAPER NUMBER
			MAIL DATE 02/21/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/373,230	Applicant(s) OKMURA ET AL.	
	Examiner Dong Jiang	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

Applicant's amendment filed on 08 November 2007 is acknowledged and entered. Following the amendment, claims 20 and 22 are amended.

Currently, claims 18-23 are pending and under consideration.

New Matter Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have not pointed out, nor can the Examiner locate, the basis in the specification for the limitations "one or more (two) amino acids are added to the N- and C- termini" (part (ii)), and "one or more amino acids in the N- and C- termini" (part (iii)) in claims 18 and 20. Further, Applicants have not pointed out, nor can the Examiner locate, the basis in the specification for the limitation "one or two amino acids" in part (ii) of claim 20.

This is a new matter rejection.

Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is indefinite and confusing for the recitation "(i) ... replaced ..., (ii) ... added to the N- and C- termini ..., and/or (iii) ... in the N- and C- termini ... deleted ..." because it is unclear whether such a limitation indicates that (i) to (iii) can happen in the same time, if so, what it means by addition *and* deletion in the N- and C- termini (parts (ii) and (iii)). The metes and bounds of the claim, therefore, cannot be determined. Claim 20 is similarly indefinite.

Claim 22 is indefinite because the claim merely recites "as a variant of ... SEQ ID NO:2", having the physical and biological properties of SEQ ID NO:2, and it does not define any variation in any way. The metes and bounds of the claim, therefore, cannot be determined.

The remaining claims are rejected for depending from an indefinite claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-23 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention., for the reasons of record set forth in the last Office Action mailed on 08 August 2007, at pages 3-5.

Applicants argument filed on 08 November 2007 has been fully considered, but is not deemed persuasive for the reasons below.

At pages 7-8 of the response, the applicant argues that an isolated variant of IL-18 is limited by its amino acid sequences (see parts (i) to (iii) of claim 20), its function of inducing IFN- γ production, its purity (i.e., exhibits a single protein band on SDS-PAGE), and its MW, that one of skill in the art could have easily obtained such a variant as defined in claims 20 or 22, once the amino acid sequence of SEQ ID NO:2 was given, based on the recombinant DNA technology known to the public at the time of the present application was filed (citing the J.D Watson ref and two US patents). This argument is not persuasive because the issue is not

whether the recombinant DNA technology was known to the public, rather, the issue is that the present application does not provide adequate written description for the claimed genus (the claims read on functional equivalent of IL-18), and one of skill in the art cannot envision the detailed chemical structure of the encompassed variants. As addressed in the last Office Action, the specification merely discloses *one* IL-18 amino acid sequence with particularity, the murine IL-18 of SEQ ID NO:2 (with one particular substitution), and no particular variant of the IL-18 with amino acid addition, deletion, substitution, or any other type of “functional equivalents” meeting the limitations of these claims were ever identified or particularly described. However, the claims encompass variants having “one or more” amino acid replaced (claim 18, part (i), for example), which requires no sequence similarity to the disclosed SEQ ID NO:2, therefore, reads on “functional equivalents”. Under such condition, none of other limitations (MW, purity, activity) provides sufficient distinguishing identifying characteristics of the genus. It is further noted that claim 20 does not even define any structural variation of “a variant”. As such, a skilled artisan cannot begin to imagine what molecules and their chemical structures are being claimed.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. Therefore, only the polypeptide of SEQ ID NO:2, but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Conclusion:

No claim is allowed.

Application/Control Number:
09/373,230
Art Unit: 1646

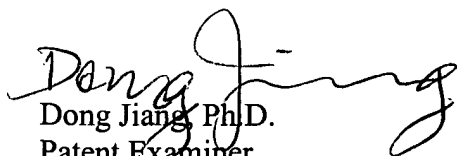
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Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Dong Jiang, Ph.D.
Patent Examiner
AU1646
2/18/08

8/12/99

In re of OKAMURA=2

- ☐ Any additional fee required by the filing of an enclosed preliminary or supplemental preliminary amendment (for entry after calculation of the filing fee) has been calculated as shown below:

	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	CALCULATION
TOTAL		-	=	X \$18.00	\$
INDEP		-	=	x 78.00	\$
<input type="checkbox"/> Multiple Dependent Claim Presented				x \$260.00	\$
Total of Above Calculations =					\$
Reduction by 1/2 for filing by small entity					-\$
Total Additional Fee =					\$

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- ☐ Other Fees: _____
- ☐ Other Attachments: _____
- ☒ Return Receipt Postcard (in duplicate)

The following statements are applicable:

- ☐ The benefit under 35 U.S.C. §119 is claimed of the filing date of:
Application No. 184162/1994 in Japan on July 14, 1994. A certified copy of said priority document ☐ is attached ☒ was filed in progenitor case 08/502,535 on November 8, 1995;
Application No. 45057/1995 in Japan on February 10, 1995. A certified copy of said priority document ☐ is attached ☒ was filed in progenitor case 08/502,535 on November 8, 1995;
- ☒ The present application is a ☐ Continuation ☒ Division
☐ Continuation-in-part of prior application No. 09/050,249.
- ☒ Incorporation By Reference. The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied herewith, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.
- ☐ A signed statement deleting inventor(s) named in the prior application is attached.
- ☒ The prior application was assigned to: KABUSHIKI KAISHA HAYASHIBARA SEIBUTSU KAGAKU KENKYUJO; 2-3, 1-chome, Shimoishii, Okayama-shi Okayama, Japan.
- ☐ Amend the specification by inserting before the first line the sentence:
--This is a ____ continuation ____ division of copending parent application Serial No. ____, filed ____--
- ☒ Certain documents were previously cited or submitted to the Patent and Trademark Office in the following prior applications 08/502,535 and 09/050,249, which is relied upon under 35 U.S.C. §120. Applicants identify these documents by attaching hereto a form PTO-1449 listing these documents, and request that they be considered and made of record in accordance with 37 CFR §1.98(d). Per Section 1.98(d), copies of these documents need not be filed in this application.